98th in a series of calls, initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19.

The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.

This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.
CDC/IDSA Clinician Call: Ending of the COVID-19 Public Health Emergency & Other Related Changes: What Clinicians Need to Know

1. Ending of the PHE: Overview & Implications for Surveillance, Infection Prevention & Control

Brendan Jackson, MD, MPH
CDR, U.S. Public Health Service
COVID-19 Response Clinical Team
Late Sequelae Unit
U.S. Centers for Disease Control and Prevention

Michael Stevens, MD, MPH, FSHEA, FIDSA, FACP
System Healthcare Epidemiologist
Associate CQO for Infection Prevention & Antimicrobial Stewardship, WVU Health System
Professor of Internal Medicine & Public Health, West Virginia University

2. Availability & Commercialization of Vaccines, Treatment

Meghan E. Pennini, PhD
Chief Vaccine and Therapeutic Officer
HHS Coordination Operations and Response Element Administration for Strategic Preparedness & Response
U.S. Department of Health and Human Services


John Farley, MD, MPH
Director, Office of Infectious Diseases
Office of New Drugs, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

4. Coverage, Costs & Payment Updates

Will Harris, JD
Senior Advisor, Office of the Administrator
Centers for Medicare & Medicaid Services

5. Q&A and Discussion

All panel members plus:
Alex J. Kallen, MD, MPH
Chief, Prevention and Response Branch
Division of Healthcare Quality Promotion
U.S. Centers for Disease Control and Prevention
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
Ending of the PHE: Overview & Implications for Surveillance, Infection Prevention & Control

Brendan Jackson, MD, MPH
CDC

Michael Stevens, MD, MPH, FSHEA, FIDSA, FACP
West Virginia University
End of COVID-19 Public Health Emergency Declaration

Implications for Public Health Surveillance, Prevention, and Control

IDSA Clinician Call

Brendan Jackson, MD, MPH
COVID-19 Incident Manager

cdc.gov/coronavirus
While the PHE ended, COVID-19 has not

End of the Federal COVID-19 Public Health Emergency (PHE) Declaration

What You Need to Know

- The federal COVID-19 PHE declaration will end on May 11, 2023.
- Most tools, like vaccines, treatments, and testing, will remain available.
- CDC’s ability to collect and share certain data will change.
- CDC is updating its guidance to align with data changes.
Hospitalizations as main way to track COVID-19 trends, new link to community guidance

Weekly Trends in COVID-19 New Hospital Admissions in The United States Reported to CDC

CDC COVID Data Tracker: Trends by Geographic Area
Emergency department visits are an excellent early indicator of spread
Another early indicator: voluntary network of laboratories that submit test data

The National Respiratory and Enteric Virus Surveillance System (NREVSS)
Third early indicator: wastewater, especially for ~40% of population covered

**CDC COVID Data Tracker: Wastewater Surveillance**

**Current SARS-CoV-2 virus levels by site, United States**

<table>
<thead>
<tr>
<th>Current virus levels category</th>
<th>Num. sites</th>
<th>% sites</th>
<th>Category change in last 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Site</td>
<td>148</td>
<td>12</td>
<td>1%</td>
</tr>
<tr>
<td>0% to 19%</td>
<td>529</td>
<td>41</td>
<td>-2%</td>
</tr>
<tr>
<td>20% to 39%</td>
<td>429</td>
<td>34</td>
<td>-12%</td>
</tr>
<tr>
<td>40% to 59%</td>
<td>149</td>
<td>12</td>
<td>-14%</td>
</tr>
<tr>
<td>60% to 79%</td>
<td>20</td>
<td>2</td>
<td>-33%</td>
</tr>
<tr>
<td>80% to 100%</td>
<td>1</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

Total sites with current data: 1276
Total number of wastewater sampling sites: 1552

[How is the current SARS-CoV-2 level compared to past levels calculated?]
Continue monitoring for new variants

### Weighted and Nowcast Estimates in United States for 2-Week Periods in 1/22/2023 – 5/13/2023

<table>
<thead>
<tr>
<th>Lineage</th>
<th>% Total</th>
<th>95% PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>XBB.1.5</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>XBB.1.5</td>
<td>80.0%</td>
<td>70.0-90.0%</td>
</tr>
<tr>
<td>XBB.1.5</td>
<td>60.0%</td>
<td>50.0-70.0%</td>
</tr>
<tr>
<td>XBB.1.5</td>
<td>40.0%</td>
<td>30.0-50.0%</td>
</tr>
<tr>
<td>XBB.1.5</td>
<td>20.0%</td>
<td>10.0-30.0%</td>
</tr>
<tr>
<td>XBB.1.5</td>
<td>0.0%</td>
<td>0.0-10.0%</td>
</tr>
</tbody>
</table>

### Nowcast Estimates in United States for 4/30/2023 – 5/13/2023

<table>
<thead>
<tr>
<th>Lineage</th>
<th>% Total</th>
<th>95% PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omicron</td>
<td>XBB.1.5</td>
<td>64.0%</td>
</tr>
<tr>
<td></td>
<td>XBB.1.6</td>
<td>14.3%</td>
</tr>
<tr>
<td></td>
<td>XBB.1.9.1</td>
<td>9.2%</td>
</tr>
<tr>
<td></td>
<td>XBB.1.9.2</td>
<td>4.0%</td>
</tr>
<tr>
<td></td>
<td>XBB.2.3</td>
<td>3.5%</td>
</tr>
<tr>
<td></td>
<td>XBB.1.5.1</td>
<td>2.4%</td>
</tr>
<tr>
<td></td>
<td>FD.2</td>
<td>1.8%</td>
</tr>
<tr>
<td></td>
<td>BQ.1.1</td>
<td>0.3%</td>
</tr>
<tr>
<td></td>
<td>CH.1.1</td>
<td>0.2%</td>
</tr>
<tr>
<td></td>
<td>XBB</td>
<td>0.2%</td>
</tr>
<tr>
<td></td>
<td>BQ.1</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>BN.1</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>BA.5</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>BA.2.12.1</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>BA.2</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>BA.2.75</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>BF.7</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>BA.5.2.6</td>
<td>0.0%</td>
</tr>
<tr>
<td>Other*</td>
<td>0.0%</td>
<td>0.0-0.0%</td>
</tr>
</tbody>
</table>

Collection date, two-week period ending
Most significant data changes with end of PHE

- Aggregate case data and national test positivity data ended
- Vaccine administration data use agreements (DUA) ended
  - Mitigated by 60+ individual DUAs
- Impacts on COVID-19 Community Levels and Transmission Levels
COVID-19 hospital admission levels replace COVID-19 Community Levels

US Reported COVID-19 New Hospital Admissions Rate per 100,000 in the Past Week, by County

Counts by hospital admission levels

<table>
<thead>
<tr>
<th>Admission Level</th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 20.0</td>
<td>10</td>
<td>0.31%</td>
</tr>
<tr>
<td>10.0 - 19.9</td>
<td>16</td>
<td>0.5%</td>
</tr>
<tr>
<td>&lt;10.0</td>
<td>3195</td>
<td>99.25%</td>
</tr>
</tbody>
</table>

CDC COVID Data Tracker: Maps by Geographic Area
Know Your COVID-19 Hospital Admission Level

Take action to protect yourself and others in your area from COVID-19.

People may choose to wear a mask at any time. Masks are recommended in indoor public transportation settings and may be required in other places by local or state authorities.

COVID-19 County Check

Find hospital admission levels and prevention steps by county. Data updated weekly.

Select a Location (all fields required)

Georgia  DeKalb County

< Start Over

Low

In DeKalb County, Georgia, the COVID-19 hospital admission level is Low.

- Stay up to date with COVID-19 vaccines.
- Maintain ventilation improvements.
- Avoid contact with people who have suspected or confirmed COVID-19.
- Follow recommendations for isolation if you have suspected or confirmed COVID-19.
- Follow the recommendations for what to do if you are exposed to someone with COVID-19.
- If you are at high risk of getting very sick, talk with a healthcare provider about additional prevention actions.

People may choose to mask at any time. People with symptoms, a positive test, or exposure to someone with COVID-19 should wear a high-quality mask or respirator when indoors in public.

If you are immunocompromised, learn more about how to protect yourself.

Find out more about the COVID-19 situation in DeKalb County, Georgia with COVID-19 Data Tracker.
With the end of the federal COVID-19 Public Health Emergency (PHE) on May 11, 2023, CDC will no longer receive data needed to publish Community Transmission levels for SARS-CoV-2. This metric informed CDC’s recommendations for broader use of source control in healthcare facilities to allow for earlier intervention, to avoid strain on a healthcare system, and to better protect individuals seeking care in these settings.

As described in CDC’s Core IPC Practices, source control remains an important intervention during periods of higher respiratory virus transmission. Without the Community Transmission metric, healthcare facilities should identify local metrics that could reflect increasing community respiratory viral activity to determine when broader use of source control in the facility might be warranted (See Appendix).
Corrections and Detention Guidance Updates

Guidance on Management of COVID-19 in Homeless Service Sites and in Correctional and Detention Facilities

Updated May 11, 2023  Español  Print
Travel guidance updates

Travelers' Health

Travelers Health › COVID-19
Testing guidance updates

COVID-19 Testing: What You Need to Know

When you get tested:

- Make sure to test at the right time
- Choose the right type of test for your circumstance
- Follow test directions as recommended by FDA

If you do not, your results may be less likely to correctly indicate whether you have COVID-19 or not.
New CDC ventilation target: 5 air changes per hour

Improving Ventilation In Buildings

What You Need to Know

- To improve ventilation in your building, keep your system operating as designed. Aim for at least 5 air changes each hour and upgrade to MERV-13 filters.

- Good ventilation is essential to maintaining a healthy indoor environment and protecting building occupants from respiratory infections.
COVID-19 Update

June 6, 2023
Michael Stevens, MD, MPH, FSHEA, FIDSA, FACP
System Healthcare Epidemiologist
COVID-19 Update

- Data reporting changes following the end of the public health emergency (PHE)
- How data will be used to inform infection prevention strategies moving forward
“Community Level” vs “Community Transmission”

**Community Level**

- For community settings
  1) New cases
  2) COVID-19 admissions
  3) % of staffed inpatient beds with COVID-19 patients

**Community Transmission**

- For healthcare settings
  1) New cases
  2) % PCR positivity
“Community Level” vs “Community Transmission”

### Community Level

![Community Level Map]

**COVID-19 Community Levels in US by County**

<table>
<thead>
<tr>
<th>Level</th>
<th>Total</th>
<th>Percent</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>67</td>
<td>2.08%</td>
<td>-0.46%</td>
</tr>
<tr>
<td>Medium</td>
<td>655</td>
<td>20.34%</td>
<td>0.13%</td>
</tr>
<tr>
<td>Low</td>
<td>2499</td>
<td>77.58%</td>
<td>0.33%</td>
</tr>
</tbody>
</table>

### Community Transmission

![Community Transmission Map]

**Community Transmission in US by County**

<table>
<thead>
<tr>
<th>Type</th>
<th>Total</th>
<th>Percent</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>2416</td>
<td>74.98%</td>
<td>-1.83%</td>
</tr>
<tr>
<td>Substantial</td>
<td>468</td>
<td>14.53%</td>
<td>-0.12%</td>
</tr>
<tr>
<td>Moderate</td>
<td>218</td>
<td>6.77%</td>
<td>0.62%</td>
</tr>
<tr>
<td>Low</td>
<td>120</td>
<td>3.72%</td>
<td>1.33%</td>
</tr>
</tbody>
</table>

cdc.gov; data updated 2/22/23
Data Updates with the End of the Public Health Emergency (PHE)

(Still) Available
• COVID-19 hospital admissions
• COVID-19 deaths
• Emergency Department patient visits with COVID-19
• COVID-19 test positivity
• Wastewater surveillance
• Genomic surveillance
• Count of COVID-19 vaccines administered

Retired
• COVID-19 case and death data (county/state data)
• County-level test positivity data
• V-safe tracking system

Although COVID-19 cases and associated hospitalizations have decreased in recent months, COVID-19 remains an ongoing public health challenge.

- Hospital admissions: 
  - Track: Spread in communities + severity of illness

- Death certificates: 
  - Track: Severity of illness

- Emergency department visits: 
  - Track: Early signs of spread

- Genomic sequencing: 
  - Tracks: New variants

Check COVID.cdc.gov to know when to take action

*To account for changes in available data after the end of the U.S. Public Health Emergency declaration

bit.ly/mmwr7219e1

MAY 5, 2023
# SARS-CoV-2 Data That Are Still Available Following the End of the PHE

<table>
<thead>
<tr>
<th>Data</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 hospital admissions</td>
<td>• Hospitals required to report through April 2024</td>
</tr>
<tr>
<td></td>
<td>• Data shifted from daily to weekly reporting</td>
</tr>
<tr>
<td></td>
<td>• Allows for county-level tracking of severe COVID-19</td>
</tr>
<tr>
<td>COVID-19 deaths</td>
<td>• Source of data has changed; now from the National Vital Statistics System (NVSS)</td>
</tr>
<tr>
<td>Emergency Department patient visits with diagnosed COVID-19</td>
<td>• Data from the National Syndromic Surveillance Program (NSSP); Includes about three-quarters of US ERs</td>
</tr>
<tr>
<td>COVID-19 (NAAT) test positivity</td>
<td>• Source of data has changed; after May 25 = from the National Respiratory and Enteric Virus Surveillance System (NREVSS): over 450 labs that voluntarily submit data</td>
</tr>
<tr>
<td>Wastewater surveillance</td>
<td></td>
</tr>
<tr>
<td>Genomic surveillance</td>
<td>• Reporting biweekly</td>
</tr>
<tr>
<td>Count of COVID-19 vaccines administered</td>
<td>• Continues “for jurisdictions who continue to submit data”</td>
</tr>
<tr>
<td></td>
<td>• Data now being updated monthly (not weekly)</td>
</tr>
</tbody>
</table>

COVID Data Tracker

Weekly Update for the United States

**Hospitalizations**
- Hospital Admissions (In Past Week): 8,256
- Trend in Hospital Admissions: -11% in past week

**Deaths**
- % Due to COVID-19 (In Past Week): 1.3%
- Trend in % COVID-19 Deaths: -13.3% in past week

**Vaccinations**
- % with Updated Booster Dose: 17.0%

<table>
<thead>
<tr>
<th>Total Hospitalizations</th>
<th>Total Deaths</th>
<th>Total Updated Booster Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>6,161,377</td>
<td>1,129,838</td>
<td>56,478,510</td>
</tr>
</tbody>
</table>

CDC | Hospitalization data through: May 20, 2023; Death data through: May 20, 2023; Vaccination data through: May 10, 2023. Posted: May 25, 2023 6:38 PM ET
Trends in United States COVID-19 Hospitalizations, Deaths, Emergency Visits, and Test Positivity by Geographic Area

Maps, charts, and data provided by CDC, updates weekly on Thu by 8 pm ET.

View Footnotes and Download Data

Select a geographic area: West Virginia

View (left axis): Weekly COVID-19 New Hospital Admissions

View (right axis):
- Weekly COVID-19 New Hospital Admissions per 100,000
- Weekly % Deaths Due to COVID-19
- Weekly Death Rate Per 100,000 (crude)
- Weekly Death Rate Per 100,000 (age-adjusted)
- Total Deaths Per 100,000 (crude)
- Total Deaths Per 100,000 (age-adjusted)
- Weekly % ED Visits Diagnosed COVID
- Weekly % Test Positivity

The blue bars show weekly COVID-19 hospital admissions.

https://covid.cdc.gov/covid-data-tracker/#datatracker-home
SARS-CoV-2 Data That Are Still Available Following the End of the PHE

- County-level
  - Hospitalization data: admissions and inpatient and ICU bed occupancy
- State-level
  - COVID-19-associated deaths
  - ED visits for COVID-19
- HHS region-level
  - % of positive SARS-CoV-2 tests
  - Variant proportions

Silk BJ et al. MMWR 72(19):523-528; May 12, 2023.
Impact of Data Reporting Changes

- Movement to weekly reporting will create reporting lag
- Comparing “apples to oranges”
- Data submitted to NHSN on COVID-19 hospital admissions per 100,000 population is the primary surveillance indicator to help guide prevention behaviors
  - Community AND healthcare facilities

Silk BJ et al. MMWR 72(19):523-528; May 12, 2023.
Outstanding Questions

- What data will communities use to inform mitigation efforts (masking, et cetera?)
  - How and when to use these data?
- What data will healthcare facilities use to inform mitigation efforts?
  - Local (facility-specific) data versus (or +) county, state, regional and national data?
  - How and when to use these data?
- Seasonal masking in healthcare facilities
## Seasonal Masking Model: 10/1 to 3/31

<table>
<thead>
<tr>
<th>Model</th>
<th>Healthcare Providers Mask?</th>
<th>Patients Mask?</th>
<th>Visitors Mask?</th>
</tr>
</thead>
</table>
| *Respiratory Viral Seasonal Masking* Approach *October-March* | • Use state-specific CDC ILI level for October 1-March 31  
• Universal masking (HCP + Patients + Visitors) when ILI level goes above “low” for any state in the system  
• Assess ILI levels weekly and consider de-escalating IF ILI rate consistently in "low" category or lower for x2 consecutive weeks | | |
A Weekly Influenza Surveillance Report Prepared by the Influenza Division

Outpatient Respiratory Illness Activity Map Determined by Data Reported to ILINet

This system monitors visits for respiratory illness that includes fever plus a cough or sore throat, also referred to as ILI, not laboratory confirmed influenza and may capture patient visits due to other respiratory pathogens that cause similar symptoms.

2022-23 Influenza Season Week 4 ending Jan 28, 2023

[Map of the United States showing ILI activity levels with legends for Very High, High, Moderate, Low, and Minimal activity levels.]

https://gis.cdc.gov/grasp/fluview/main.html
Summary

• Major changes in data reporting have occurred with the end of the public health emergency
• Hospital admissions data represent the most comprehensive and consistent data available
  • The CDC recommends these data inform community and healthcare facility mitigation efforts
• How communities and healthcare facilities use data to inform mitigation strategies for COVID-19 is unclear at this time
Contact Information

• mike.stevens@wvumedicine.org
Availability and Commercialization of COVID Vaccines and Treatment

Meghan E. Pennini, PhD
HHS Coordination Operations and Response Element (H-CORE)
COVID-19 Therapeutics & Vaccine Distribution Updates

Meghan Pennini, Ph.D.
Chief Vaccine and Therapeutics Officer
HHS Coordination Operations and Response Element (H-CORE)

June 6, 2023

Unclassified/For Public Distribution
Public Health Emergency Declaration Expiration

White House Fact Sheet: Actions Taken by the Biden-Harris Administration to Ensure Continued COVID-19 Protections and Surge Preparedness After Public Health Emergency Transition

- Access to COVID-19 vaccines provided by the federal government are not affected in the months to come. After transition to the traditional health care market, the HHS Bridge Access Program for COVID-19 will provide access to COVID-19 vaccines and treatments for uninsured Americans.

- USG will continue to provide COVID-19 test access for the uninsured through the Increasing Community Access To Testing Program (ICATT).

- Protections that provide patients with greater access to health care remain in place (PREP Act Amendment).

- Many major telehealth flexibilities will remain in place particularly for those who struggle to find access to care.

- Continue to provide accessible information on local COVID-19 risks and continue to track emerging variants.

- Project NextGen will accelerate and streamline rapid development of the next generation of COVID-19 vaccines and treatments through public-private collaborations.

- Continue to invest in efforts to better understand and address Long COVID.

- Investments on improving indoor air quality will drive innovation in ventilation and filtration, building better protection against respiratory illnesses.
HHS Fact Sheet

HHS Fact Sheet: End of the COVID-19 Public Health Emergency

• Since January 2021, COVID-19 deaths have declined by 95%, hospitalizations down nearly 91%.
• However, many people continue to be affected by COVID-19, particularly seniors, people who are immunocompromised, and people with disabilities; our response to the spread of SARS-CoV-2 remains a public health priority.
• Americans continue to be able to access COVID-19 vaccines at no cost, just as they did during the COVID-19 PHE, due to the requirements of the CDC COVID-19 Vaccination Program Provider Agreement; people also continue to be able to access no cost COVID-19 treatments just as they have during the COVID-19 PHE.
• We will continue to work to protect Americans from the virus and its worst impacts by supporting access to COVID-19 vaccines, treatments, and tests, including for people without health insurance.
• We will continue to advance research into new, innovative vaccines and treatments through an investment of $5 billion in Project NextGen, dedicated program to accelerate and streamline rapid development of next generation vaccines and treatments
• We are continuing to invest in efforts to better understand and address Long COVID and to help mitigate the impacts.
• Once the federal government is no longer purchasing or distributing COVID-19 vaccines and treatments, payment, coverage, and access may change
Affected by the end of the COVID-19 PHE:

• Certain Medicare and Medicaid waivers and broad flexibilities for health care providers are no longer necessary and ended
  • To learn more, visit CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency - PDF
• Coverage for COVID-19 testing changed; but USG is maintaining a strong stockpile and distribution channels so that tests remain accessible at no cost in certain community locations; the USG distributed tests through COVIDtests.gov through the end of May.
• Certain COVID-19 data reporting and surveillance (e.g., case counts) changed [no change to reporting inventory/use of USG procured products]
• FDA’s ability to detect shortages of critical devices related to COVID-19 will be more limited.
• Public Readiness and Emergency Preparedness (PREP) Act liability protections were amended
# Summary of COVID-19 Preventative Agents & Treatments

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Illness</td>
<td>Per CDC Close Contact Criteria</td>
</tr>
<tr>
<td>Baseline health status, no infection</td>
<td>Not hospitalized</td>
</tr>
</tbody>
</table>

## Mild to Moderate Symptoms

<table>
<thead>
<tr>
<th>Description</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not hospitalized for COVID</td>
<td><em>Oral Antivirals</em></td>
</tr>
<tr>
<td>Hosp. for reason other than COVID</td>
<td><strong>IV Antiviral</strong></td>
</tr>
</tbody>
</table>

### *Oral Antivirals*
- **Paxlovid** (nirmatrelvir + ritonavir, Pfizer)
- **Lagevrio** (molnupiravir, Merck) – Alternative
- **Veklury** (remdesivir, Gilead)

### **IV Antiviral**
- **Veklury** (remdesivir, Gilead)

## Hospital Admission

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalized for COVID, not on oxygen</td>
<td><strong>IV Antiviral</strong></td>
</tr>
<tr>
<td>Hospitalized, on oxygen</td>
<td>Hospitalized, high flow oxygen/ non-invasive ventilation</td>
</tr>
<tr>
<td>Hospitalized, mechanical ventilation/ ECMO</td>
<td></td>
</tr>
</tbody>
</table>

## ICU Admission

<table>
<thead>
<tr>
<th>Description</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalized, for COVID, not on oxygen</td>
<td>HHS distribution; USG distribution is continuing beyond PHE</td>
</tr>
<tr>
<td>Hospitalized, on oxygen</td>
<td><strong>Commercially available</strong></td>
</tr>
<tr>
<td>Hospitalized, mechanical ventilation/ ECMO</td>
<td><strong>HHS distribution; USG distribution is continuing beyond PHE</strong></td>
</tr>
</tbody>
</table>

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1. *Convalescent Plasma EUA* https://www.fda.gov/media/141478/download
   High titer convalescent plasma is authorized for specific immunocompromised patients.
2. Refer to individual product Fact Sheets for authorization details

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### COVID-19 Vaccines

- None currently authorized for use in any U.S. state or territory.

### Reference

- Please see [NIH Current Inpatient Therapies](https://www.covid19treatmentguidelines.nih.gov/therapies/)

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*Be sure to check latest updates on inpatient care*

- **Therapeutic Management of Nonhospitalized Adults With COVID-19**
- **Therapeutic Management of Hospitalized Adults With COVID-19**
Estimated Prevalence of COVID-19 Variants Nationally

Estimates now for 2-week period and updated every 2 weeks

• XBB.1.5 remains most prevalent variant, ~54% estimated prevalence

• Several XBB sub-variants are being tracked separately, including XBB.1.16, XBB.1.9.1, XBB.2.3, XBB1.5.1, FD.2

No changes expected to therapeutics portfolio, continue to acquire data

• Paxlovid (nirmatrelvir co-packaged with ritonavir), Veklury (remdesivir), and Lagevrio (molnupiravir) are expected to retain activity against all circulating variants based on current data

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
Paxlovid (nirmatrelvir co-packaged with ritonavir)
FDA APPROVAL

- On May 25, 2023, FDA approved a New Drug Application (NDA) for Paxlovid for the treatment of mild to moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

- The Emergency Use Authorization (EUA) continues to authorize Paxlovid to treat certain eligible pediatric patients, a patient population that is not covered under the approved NDA for Paxlovid at this time.

- Paxlovid also remains authorized under EUA to ensure continued access for all eligible patients to the current supply of Paxlovid, including adult patients.

- **The product packaged under EUA** – which contains the same tablets (nirmatrelvir tablets and ritonavir tablets) as the Paxlovid that is now FDA-approved – **continues to be available from the federal government at no cost**.
COVID-19 Public Health Emergency Declaration Updates/Resources

- May 9, 2023 – FACT SHEET: Actions Taken by the Biden-Harris Administration to Ensure Continued COVID-19 Protections and Surge Preparedness After Public Health Emergency Transition | The White House
- May 9, 2023 – HHS Fact Sheet: End of the COVID-19 Public Health Emergency
- May 9, 2023 – Public Readiness and Emergency Preparedness (PREP) Act Update
- April 18, 2023 – HHS Fact Sheet: HHS Announces ‘HHS Bridge Access Program For COVID-19 Vaccines and Treatments’ to Maintain Access to COVID-19 Care for the Uninsured
- FAQs: What Happens to EUAs When a Public Health Emergency Ends (FDA)
- ASPR FAQ (ASPR)
- PREP Act Questions and Answers (ASPR)
- PREP Act Coverage and Mpox: Frequently Asked Questions (ASPR)
- Medical Countermeasure Commercialization (ASPR TRACIE)
Moving from Emergency Use Authorization to Approval of COVID-19 Treatments: Paxlovid Update

John Farley, MD, MPH
U.S. Food & Drug Administration
FDA Update – Approval of Paxlovid

John Farley, MD MPH
Director, Office of Infectious Diseases
Office of New Drugs, Center for Drug Evaluation and Research

June 6, 2023
Paxlovid Approved, EUA Continues (1)

• On May 25, FDA approved Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

• The EUA continues to authorize Paxlovid for emergency use to treat certain eligible pediatric patients, a patient population that is not covered under the approved NDA for Paxlovid at this time.
Paxlovid Approved, EUA Continues (2)

• Paxlovid also remains authorized under EUA to ensure continued access for all eligible patients to the U.S. government’s supply of EUA packaged Paxlovid, including adult patients who are the subject of the approved NDA, pending commercial launch of the approved product.

• The EUA is the current mechanism for Paxlovid access. The use of Paxlovid under the EUA must be consistent with the terms and conditions of the authorization.

FDA FAQs on the Emergency Use Authorization for Paxlovid
Patients With Prior/Acquired Immunity

• Among patients in EPIC-HR who were antibody positive at trial enrollment, the risk of COVID-19-related hospitalization or death from any cause during 28 days of follow-up was 0.2% among those treated with Paxlovid compared with 1.7% of those receiving placebo.

• EPIC-SR enrolled vaccinated patients with at least one risk factor for progression to severe COVID-19 (and unvaccinated without a risk factor). Among these vaccinated patients, there was a reduction in the risk of COVID-19 related hospitalization or death from any cause with use of PAXLOVID versus placebo, although not statistically significant.
COVID-19 Rebound

• EPIC-HR and EPIC-SR were both randomized placebo-controlled trials, and these trials provide useful data to assess COVID-19 rebound.

• Data from these two trials showed that rebound in SARS-CoV-2 (RNA or virus) shedding or self-reported COVID-19 symptoms occurred in a subset of patients and happened at similar rates in both the patients receiving Paxlovid and placebo.

• Based on the data currently available to FDA, there is not a clear association between Paxlovid treatment and COVID-19 rebound.
Drug-Drug Interactions

• Prior to prescribing Paxlovid, health care providers must: 1) review all medications taken by the patient to assess potential drug-drug interactions with a strong CYP3A inhibitor like Paxlovid and 2) determine if medications require a dose adjustment, interruption, and/or additional monitoring if taken at the same time as Paxlovid.

• Resources for health care providers: Prescribing Information, EUA Fact Sheet, Prescriber Screening Checklist, NIH COVID-19 Treatment Guidelines, IDSA COVID-19 Treatment Guidelines, Liverpool COVID-19 Drug Interactions Checker
Coverage, Costs & Payment Updates

Will Harris, JD
Centers for Medicare & Medicaid Services
Q&A/ Discussion
Selected Resources

**Program Links:**
- This webinar is being recorded and can be found with the slides online at [https://www.idsociety.org/cliniciancalls](https://www.idsociety.org/cliniciancalls)

**Dr. Jackson**
- [https://covid.cdc.gov/COVID-data-tracker/#trends_weeklyhospitaladmissions_select_00](https://covid.cdc.gov/COVID-data-tracker/#trends_weeklyhospitaladmissions_select_00)
- [https://www.cdc.gov/surveillance/nrevss/index.html](https://www.cdc.gov/surveillance/nrevss/index.html)

**Dr. Stevens**
- [https://gis.cdc.gov/grasp/fluview/main.html](https://gis.cdc.gov/grasp/fluview/main.html)
Selected Resources - Cont.

Dr. Pennini

- [https://www.cdc.gov/icatt/index.html](https://www.cdc.gov/icatt/index.html)
- [https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html](https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html)
- [https://www.covid19treatmentguidelines.nih.gov/therapies/](https://www.covid19treatmentguidelines.nih.gov/therapies/)
- [https://www.aspr.hhs.gov/legal/PREPact/Pages/default.aspx](https://www.aspr.hhs.gov/legal/PREPact/Pages/default.aspx)
Dr. Pennini – cont.
• https://aspr.hhs.gov/COVID-19/Pages/COVID_FAQs.aspx
• https://aspr.hhs.gov/legal/PREPact/Pages/PREP-Act-Question-and-Answers.aspx#COVID
• https://asprtracie.hhs.gov/technical-resources/159/medical-countermeasure-commercialization/0

Dr. Farley
• https://www.fda.gov/media/155052/download
• https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217188s000lbl.pdf
• https://www.fda.gov/media/155050/download
• https://www.fda.gov/media/158165/download
• https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/whats-new/
• https://www.covid19-druginteractions.org/

Mr. Harris
THANK YOU

We want to hear from you!
Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at
www.idsociety.org/cliniciancalls
-- library of all past calls available --

Contact Us:
Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)